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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,206	06/26/2001	Nigel D. Atherton	PHARMA-131	9337

24999 7590 10/21/2003

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,206

Applicant(s)

Atherton et al.

Examiner

PAK, J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/29/03
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 5-19, 22-24 and 26-40 is/are pending in the application.
- 4a) Of the above, claim(s) 22 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 13-17, 23-24 and 34-35 is/are rejected.
- 7) ☒ Claim(s) 2, 9-12, 18-19, 26-32 and 36-40 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Claims 1-2, 5-19, 22-24 and 26-40 are pending in this application.

Claims 22 and 33 stand withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-2, 5-19, 23-24, 26-32 and 34-40 will presently be examined to the extent that they read on all lanthanum (III) compounds.

Claims 5, 6, 7, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 5 and 6 recite (in the new amendatory format), "method according to claim 2 4 wherein" Note, there is no conjunction such as "and" or "or" between the two claims. Therefore, the claim dependency is unclear. Several alternatives such as "2 or 4," "2 and 4," and "24" are possible. Clarification is needed. Claim 7 is included here because it depends on claim 6.

(2) Claims 34 and 35 recite "said lanthanum (III) compound" (emphasis added). However, there is no antecedent basis for lanthanum (III) compound. Both claims from which claims 34 and 35 depend do not specifically require the lanthanum compound to be lanthanum (III) compound.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8, 13-17, 23-24 are rejected under 35 USC 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as obvious over DRUGU abstract 1987-06492.

DRUGU abstract 1987-06492 explicitly discloses lanthanum (III) – HDA – HQ as having antiinflammatory activity in subacute and chronic inflammation in rats with formaldehyde induced arthritis.

It is recognized that the cited reference does not expressly state that the administered lanthanum (III) compound was recognized to provide all of the claimed effects on bone. However, the same lanthanum (III) compound was administered to the same subject (rats, which are mammals) that suffered from the same bone disorders, i.e. either bone deficit condition associated with bone chemotherapy treatment or osteoarthritis¹. Further, therapeutic benefit was obtained after treatment. Under these facts, it is the Examiner's position that since the same compound was administered to the same subject, the same effect must necessarily have been obtained. In re Best, 195 USPQ 430, 433 (CCPA 1977); In re May, 197 USPQ 601 (CCPA 1978); Ex parte

¹ Osteoarthritis is a degenerative joint disease characterized by breakdown of the joint's cartilage. Arthritis induced by formaldehyde would fall under such classification type.

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Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Int. 1993). A rejection under the alternative grounds of 102 or 103 is therefore appropriate. MPEP 2112.02.

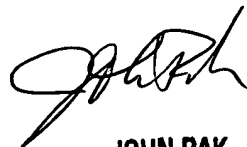
For these reasons, these claims must be refused. No claim is allowed.

Claims 2, 9-12, 18-19, 26-32 and 36-40 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form, which incorporates all of the features of base claim(s), subject to a search update at the time of the next Office Action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
PRIMARY EXAMINER
GROUP 1600